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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,269	01/12/2001	Satoshi Iuchi	3914-3	9211

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 05/23/2003

21

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/758,269

Applicant(s)

IUCHI ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The Amendment filed February 13, 2003, paper no.19, has been entered.

Claims 2-4 are cancelled.

Claims 1, 5-10, 13-14 are newly amended.

Claims 15-22 are newly added.

Claims 1 and 5-22 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claims 1 and 5-14 remain rejected, and claims 15-17 and 19-22 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the *Arabidopsis* AtNCED3 DNA comprising the nucleotide sequence of SEQ ID NO:5 encoding an amino acid sequence of SEQ ID NO:6, and a method for increasing or decreasing drought stress tolerance in *Arabidopsis* by transforming *Arabidopsis* plants with the *Arabidopsis* AtNCED3 DNA comprising the nucleotide sequence of SEQ ID NO:5 encoding an amino acid sequence of SEQ ID NO:6, does not reasonably provide enablement for other DNA molecules, or for methods of increasing or decreasing other types of stress tolerance in other species of plants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed August 13, 2002.

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Applicants' arguments filed February 13, 2003, have been fully considered but they are not persuasive.

Applicants argue that the specification teaches at page 38 that their invention would be equally useful for stresses other than drought, and that since the AtNCED3 gene is induced by stresses other than drought, one skilled in the art would recognize that the instant invention is equally effective for improving tolerance to other stresses as well, and that such effectiveness could easily be shown by routine experimentation (reply page 8).

The Office maintains that it would require undue experimentation for one skilled in the art to determine how to use the claimed sequences to affect tolerance to stresses other than drought, as the specification provides no guidance with respect to how to express the claimed sequences in a manner that affects tolerance to other stresses. The Office further maintains that one skilled in the art would not recognize that the instant invention is equally effective for improving tolerance to other stresses on the basis that the AtNCED3 gene is induced by stresses other than drought, as one skilled in the art would recognize that a correlation between stress conditions and the induction of gene expression does not always indicate that the product of the induced gene is involved in affecting stress tolerance.

Applicants also argue that the invention as now claimed is focused on a limited number of sequences, and that one skilled in the art could isolated such sequences without undue experimentation. Applicants point out that the claims as amended do not include all modifications of the amino acid sequence of SEQ ID NO:6, but only a narrow subset thereof, all of which retain the function of the wild-type protein. Applicants argue that the operable

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embodiments can easily be distinguished from the inoperative embodiments by using the enzyme assay described in the specification. Applicants additionally argue that the identification of optimal expression levels needed to achieve the desired result would be within the skill of the art, and would involve only routine experimentation (reply pages 8-9).

The Office acknowledges that the claims as amended are narrower in scope, but maintains that it would require undue experimentation for one skilled in the art to determine which sequences to use to affect stress tolerance in transgenic plants, as the specification provides no guidance with respect to which of the 599 amino acids of SEQ ID NO:6 could be conservatively substituted without affecting the function of protein, or with respect to which of the 599 amino acids of SEQ ID NO:6 would need to be retained by a protein comprising an amino acid sequence at least 80% identical to SEQ ID NO:6 in order for that protein to retain the function of SEQ ID NO:6. The undue experimentation lies in the trial and error process of selecting sequences for testing using the enzyme assay described in the specification, not in the performance of the assay itself. Accordingly, absent guidance with respect to which amino acid sequences correspond to functional proteins, it would also require undue experimentation to determine which amino acid sequences to express to affect stress tolerance in a transgenic plant.

Finally, with respect to the issue of how the same DNA could both increase and decrease the amount of abscisic acid or stress tolerance in transgenic plants, Applicants argue that the claims are enabled when read in light of the specification, which describes adequately both an increase and a decrease in drought stress tolerance as a consequence of expressing the claimed sequence (reply pages 9-10).

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The Office acknowledges that the specification describes both an increase and a decrease in drought stress tolerance as a consequence of expressing an isolated nucleic acid of SEQ ID NO:5 in transgenic plants, but maintains that both effects were not achieved using a single method. The Office maintains that the specification discloses two separate methods for increasing and decreasing drought stress tolerance in a transgenic plant, a method for increasing drought stress tolerance by expressing SEQ ID NO:5 in a sense orientation, and a method for decreasing drought stress tolerance by expressing SEQ ID NO:5 in an anti-sense orientation. The Office further maintains that it would require undue experimentation for one skilled in the art to achieve both effects using a single method as the specification provides no guidance with respect to how to make and use a vector capable of producing both effects when used in a single method.

Claims 1, 7 and 19, and claims 5-13 and 15-18 dependent thereon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7 and 19 are indefinite in the recitation of "gene". The word gene implies DNA existing in nature that includes coding regions and noncoding regions, such as enhancers, promoters, and introns. It is suggested that the claim be amended to recite "isolated polynucleotide" or "isolated nucleic acid"

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC

May 19, 2003

Phuong Bui
PHUONG T. BUI 5/19/03
PRIMARY EXAMINER